According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9372657-00008
 Date of first issue: 27.08.2021

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Pentobarbital Sodium / Phenytoin Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub- : Veterinary product

stance/Mixture

Recommended restrictions :

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

Walton Manor, Walton

MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Flammable liquids, Category 3 H226: Flammable liquid and vapour.

Acute toxicity, Category 3 H301: Toxic if swallowed.

Skin sensitisation, Category 1 H317: May cause an allergic skin reaction.
Carcinogenicity, Category 2 H351: Suspected of causing cancer if swallowed.
Reproductive toxicity, Category 2 H361: Suspected of damaging fertility or the un-

born child.

Specific target organ toxicity - single ex- H370: Causes damage to organs.

posure, Category 1

Specific target organ toxicity - repeated

exposure, Category 2

Long-term (chronic) aquatic hazard, Cat-

egory 3

H373: May cause damage to organs through pro-

1075. May cause damage to organs imough pro-

longed or repeated exposure.

H412: Harmful to aquatic life with long lasting ef-

fects.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9372657-00008
 Date of first issue: 27.08.2021

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Hazard pictograms :







Signal word : Danger

Hazard statements : H226 Flammable liquid and vapour.

H301 Toxic if swallowed.

H317 May cause an allergic skin reaction.
 H351 Suspected of causing cancer if swallowed.
 H361 Suspected of damaging fertility or the unborn

child.

H370 Causes damage to organs.

H373 May cause damage to organs through prolonged

or repeated exposure.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P210 Keep away from heat, hot surfaces, sparks, open

flames and other ignition sources. No smoking.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye

protection/ face protection.

Response:

P301 + P310 + P330 IF SWALLOWED: Immediately call a

POISON CENTER/ doctor. Rinse mouth.

P308 + P311 IF exposed or concerned: Call a POISON

CENTER/ doctor.

Hazardous components which must be listed on the label:

Pentobarbital sodium Phenytoin sodium Benzyl alcohol

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Vapours may form explosive mixture with air.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9372657-00008
 Date of first issue: 27.08.2021

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Pentobarbital sodium	57-33-0 200-323-9	Acute Tox. 3; H301 Repr. 2; H361d STOT SE 1; H370 (Central nervous system) Aquatic Chronic 3; H412	>= 30 - < 50
Ethanol#	64-17-5 200-578-6 603-002-00-5	Flam. Liq. 2; H225 Eye Irrit. 2; H319 ————————————————————————————————————	>= 10 - < 20
Phenytoin sodium	630-93-3 211-148-2	Acute Tox. 3; H301 Skin Sens. 1; H317 Carc. 2; H351 Repr. 2; H361 STOT RE 1; H372 (Central nervous system)	>= 3 - < 10
Benzyl alcohol	100-51-6 202-859-9 603-057-00-5	Acute Tox. 4; H302 Eye Irrit. 2; H319 Skin Sens. 1B; H317	>= 1 - < 10
Substances with a workplace exposure limit :			
Propylene glycol	57-55-6 200-338-0		>= 10 - < 20

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

^{#:} Voluntarily-disclosed substance

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 28.09.2024 9372657-00008 Date of first issue: 27.08.2021 4.0

advice.

Protection of first-aiders First Aid responders should pay attention to self-protection,

> and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed If swallowed, DO NOT induce vomiting.

Call a physician or poison control centre immediately.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks Toxic if swallowed.

> May cause an allergic skin reaction. Suspected of causing cancer if swallowed.

Suspected of damaging fertility or the unborn child.

Causes damage to organs.

May cause damage to organs through prolonged or repeated

exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-: Do not use a solid water stream as it may scatter and spread

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.0 28.09.2024 9372657-00008 Date of first issue: 27.08.2021

fighting fire

Flash back possible over considerable distance. Vapours may form explosive mixtures with air.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- :

ucts

Carbon oxides

Nitrogen oxides (NOx)

Metal oxides

5.3 Advice for firefighters

Special protective equipment :

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Remove all sources of ignition.

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g. by containment or oil

barriers).

Retain and dispose of contaminated wash water.

If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Non-sparking tools should be used.

Soak up with inert absorbent material.

Suppress (knock down) gases/vapours/mists with a water

spray jet.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9372657-00008
 Date of first issue: 27.08.2021

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Use explosion-proof electrical, ventilating and lighting equip-

ment.

Advice on safe handling : Do not get on skin or clothing.

Do not breathe mist or vapours.

Do not swallow.

Avoid contact with eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Non-sparking tools should be used. Keep container tightly closed.

Keep away from heat, hot surfaces, sparks, open flames and

other ignition sources. No smoking.

Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace.

Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

: Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Keep

away from heat and sources of ignition.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9372657-00008
 Date of first issue: 27.08.2021

Organic peroxides Flammable solids Pyrophoric liquids Pyrophoric solids

Self-heating substances and mixtures

Substances and mixtures, which in contact with water, emit

flammable gases Explosives

Gases

Very acutely toxic substances and mixtures

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Pentobarbital sodi- um	57-33-0	TWA	40μg/m3 (OEB3)	Internal
		Wipe limit	400µg/100cm2	Internal
Propylene glycol	57-55-6	TWA (Total va- pour and parti- cles)	150 ppm 474 mg/m3	GB EH40
		TWA (particles)	10 mg/m3	GB EH40
Ethanol	64-17-5	TWA	1,000 ppm 1,920 mg/m3	GB EH40
Phenytoin sodium	630-93-3	TWA	50 μg/m3 (OEB3)	Internal
		Wipe limit	500 μg/100 cm2	Internal

Derived No Effect Level (DNEL)

Substance name	End Use	Exposure routes	Potential health effects	Value
Propylene glycol	Workers	Inhalation	Long-term local ef- fects	10 mg/m3
	Workers	Inhalation	Long-term systemic effects	168 mg/m3
	Consumers	Inhalation	Long-term local ef- fects	10 mg/m3
	Consumers	Inhalation	Long-term systemic effects	50 mg/m3
Ethanol	Workers	Inhalation	Long-term systemic effects	380 mg/m3
	Workers	Skin contact	Long-term systemic effects	267 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic	114 mg/m3

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9372657-00008
 Date of first issue: 27.08.2021

			effects	
Benzyl alcohol	Workers	Inhalation	Long-term systemic effects	22 mg/m3
	Workers	Inhalation	Acute systemic effects	110 mg/m3
	Workers	Skin contact	Long-term systemic effects	8 mg/kg bw/day
	Workers	Skin contact	Acute systemic ef- fects	40 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	5.4 mg/m3
	Consumers	Inhalation	Acute systemic ef- fects	27 mg/m3
	Consumers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Skin contact	Acute systemic ef- fects	20 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Ingestion	Acute systemic ef- fects	20 mg/kg bw/day

Predicted No Effect Concentration (PNEC)

Substance name	Environmental Compartment	Value
Propylene glycol	Fresh water	260 mg/l
	Freshwater - intermittent	183 mg/l
	Marine water	26 mg/l
	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg dry weight (d.w.)
	Marine sediment	57.2 mg/kg dry weight (d.w.)
	Soil	50 mg/kg dry weight (d.w.)
Ethanol	Fresh water	0.96 mg/l
	Freshwater - intermittent	2.75 mg/l
	Marine water	0.79 mg/l
	Sewage treatment plant	580 mg/l
	Fresh water sediment	3.6 mg/kg dry weight (d.w.)
	Marine sediment	2.9 mg/kg dry weight (d.w.)
	Soil	0.63 mg/kg dry weight (d.w.)
	Oral (Secondary Poisoning)	380 mg/kg food
Benzyl alcohol	Fresh water	1 mg/l
	Marine water	0.1 mg/l
	Intermittent use/release	2.3 mg/l
	Sewage treatment plant	39 mg/l
	Fresh water sediment	5.27 mg/kg
	Marine sediment	0.527 mg/kg
	Soil	0.456 mg/kg

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9372657-00008
 Date of first issue: 27.08.2021

8.2 Exposure controls

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

Use explosion-proof electrical, ventilating and lighting equipment.

Personal protective equipment

Eye/face protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving. Take note that the product is flam-

mable, which may impact the selection of hand protection.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable

suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Equipment should conform to BS EN 14387

Filter type : Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : liquid Colour : pink

Odour : No data available Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling : No data available

range

Flash point : 44 - 60 °C

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 28.09.2024 9372657-00008 Date of first issue: 27.08.2021 4.0

Evaporation rate No data available

Flammability (solid, gas) Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure No data available

Relative vapour density No data available

No data available Relative density

No data available Density

Solubility(ies)

Water solubility Partition coefficient: n-

octanol/water

No data available No data available

Auto-ignition temperature No data available

Decomposition temperature No data available

Viscosity

Viscosity, kinematic No data available

Explosive properties Not explosive

Oxidizing properties The substance or mixture is not classified as oxidizing.

9.2 Other information

Flammability (liquids) Not applicable

Molecular weight No data available

Particle size No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.0 28.09.2024 9372657-00008 Date of first issue: 27.08.2021

Hazardous reactions : Flammable liquid and vapour.

Vapours may form explosive mixture with air. Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of:

exposure

: Inhalation Skin contact

Ingestion Eye contact

Acute toxicity

Toxic if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 261.66 mg/kg

Method: Calculation method

Components:

Pentobarbital sodium:

Acute oral toxicity : LD50 (Rat): 118 mg/kg

LD50 (Mouse): 239 mg/kg

LD50 (Rabbit): 175 mg/kg

LD50 (Dog): 65 mg/kg

Ethanol:

Acute oral toxicity : LD50 (Rat): 10,470 mg/kg

Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat, male): 116.9 mg/l

Exposure time: 4 h
Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rabbit): > 15,800 mg/kg

Phenytoin sodium:

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9372657-00008
 Date of first issue: 27.08.2021

Acute oral toxicity : Acute toxicity estimate: 100 mg/kg

Method: Expert judgement

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1,200 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.4 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Assessment: The substance or mixture has no acute inhala-

tion toxicity

Propylene glycol:

Acute oral toxicity : LD50 (Rat): 22,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 44.9 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Assessment: The substance or mixture has no acute dermal

toxicity

Skin corrosion/irritation

Not classified based on available information.

Components:

Ethanol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Propylene glycol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Ethanol:

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.0 28.09.2024 9372657-00008 Date of first issue: 27.08.2021

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

Propylene glycol:

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

Ethanol:

Test Type : Mouse ear swelling test (MEST)

Exposure routes : Skin contact
Species : Mouse
Result : negative

Phenytoin sodium:

Assessment : Probability or evidence of skin sensitisation in humans

Benzyl alcohol:

Test Type : Human repeat insult patch test (HRIPT)

Exposure routes : Skin contact
Species : Humans
Result : positive

Assessment : Probability or evidence of low to moderate skin sensitisation

rate in humans

Propylene glycol:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9372657-00008
 Date of first issue: 27.08.2021

Germ cell mutagenicity

Not classified based on available information.

Components:

Ethanol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Rat

Application Route: Ingestion

Result: negative

Phenytoin sodium:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro sister chromatid exchange assay in mam-

malian cells Result: positive

Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Benzyl alcohol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.0 28.09.2024 9372657-00008 Date of first issue: 27.08.2021

Result: negative

Propylene glycol:

Genotoxicity in vitro Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Genotoxicity in vivo Test Type: Mammalian erythrocyte micronucleus test (in vivo

> cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Carcinogenicity

Suspected of causing cancer if swallowed.

Components:

Phenytoin sodium:

Species Rat Application Route : Ingestion Exposure time 2 Years Result : negative

Species Mouse Application Route Ingestion Exposure time 2 Years Result positive

ment

Carcinogenicity - Assess- : Limited evidence of carcinogenicity in animal studies (oral)

Benzyl alcohol:

Species Mouse Application Route Ingestion Exposure time 103 weeks

Method OECD Test Guideline 451

Result negative

Propylene glycol:

Species Rat Application Route Ingestion Exposure time 2 Years Result negative

Reproductive toxicity

Suspected of damaging fertility or the unborn child.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9372657-00008
 Date of first issue: 27.08.2021

Components:

Pentobarbital sodium:

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

Ethanol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Mouse

Application Route: Ingestion

Result: negative

Phenytoin sodium:

Effects on fertility : Test Type: reproductive and developmental toxicity study

Species: Rat

Application Route: Ingestion

Result: positive

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: reproductive and developmental toxicity study

Species: Rat

Application Route: Ingestion

Result: positive

Remarks: Based on data from similar materials

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on sexual function and

fertility, and/or on development, based on animal experiments.

Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Ingestion

Result: negative

Propylene glycol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Mouse

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Ingestion

Result: negative

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9372657-00008
 Date of first issue: 27.08.2021

II

STOT - single exposure

Causes damage to organs.

Components:

Pentobarbital sodium:

Exposure routes : Ingestion

Target Organs : Central nervous system
Assessment : Causes damage to organs.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Phenytoin sodium:

Exposure routes : Ingestion

Target Organs : Central nervous system

Assessment : Shown to produce significant health effects in animals at con-

centrations of 10 mg/kg bw or less.

Repeated dose toxicity

Components:

Ethanol:

Species : Rat

NOAEL : 1,730 mg/kg
LOAEL : 3,200 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Phenytoin sodium:

Species : Rat

NOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks

Remarks : Based on data from similar materials

Species : Mouse

NOAEL : > 10 - 100 mg/kg LOAEL : > 10 - 100 mg/kg

Application Route : Ingestion Exposure time : 13 Weeks

Remarks : Based on data from similar materials

Benzyl alcohol:

Species : Rat NOAEL : 1.072 mg/l

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.0 28.09.2024 9372657-00008 Date of first issue: 27.08.2021

Application Route inhalation (dust/mist/fume)

Exposure time 28 Davs

Method **OECD Test Guideline 412**

Propylene glycol:

Species Rat, male NOAEL >= 1,700 mg/kgApplication Route Ingestion Exposure time : 2 yr

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Pentobarbital sodium:

Ingestion Symptoms: dry mouth, mood swings, Dizziness, Headache,

Nausea, central nervous system effects, Sweating

Phenytoin sodium:

Ingestion Symptoms: Nausea, constipation, confusion, Vomiting, central

nervous system effects, Dizziness, insomnia, Blood disorders,

Liver disorders, Tremors, anorexia

SECTION 12: Ecological information

12.1 Toxicity

Components:

Pentobarbital sodium:

LC50 (Pimephales promelas (fathead minnow)): 49.5 mg/l Toxicity to fish

Exposure time: 96 h

Ethanol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 14,200 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Ceriodaphnia dubia (water flea)): 5,012 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l

Exposure time: 72 h

EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l

Exposure time: 72 h

EC50 (Protozoa): 5,800 mg/l Toxicity to microorganisms

Exposure time: 4 h

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 28.09.2024 9372657-00008 Date of first issue: 27.08.2021 4.0

Toxicity to fish (Chronic tox-

icity)

NOEC: >= 79 mg/l

Exposure time: 100 d

Species: Oryzias latipes (Japanese medaka)

Toxicity to daphnia and other: aquatic invertebrates (Chron-

ic toxicity)

NOEC: 9.6 mg/l Exposure time: 9 d

Species: Daphnia magna (Water flea)

Phenytoin sodium:

EC50 (Danio rerio (zebra fish)): > 10 - 100 mg/l Toxicity to fish

Exposure time: 72 h

Remarks: Based on data from similar materials

aquatic invertebrates

Toxicity to daphnia and other : Remarks: No toxicity at the limit of solubility

Benzyl alcohol:

Toxicity to fish LC50 (Pimephales promelas (fathead minnow)): 460 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 230 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 770

ma/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 51 mg/l

Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

Propylene glycol:

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l

Exposure time: 96 h

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 20,000 mg/l

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9372657-00008
 Date of first issue: 27.08.2021

Exposure time: 18 h

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 13,020 mg/l Exposure time: 7 d

Species: Ceriodaphnia dubia (water flea)

12.2 Persistence and degradability

Components:

Ethanol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 84 % Exposure time: 20 d

Phenytoin sodium:

Biodegradability : Result: Not readily biodegradable.

Method: OECD Test Guideline 301C

Remarks: Based on data from similar materials

Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 92 - 96 % Exposure time: 14 d

Propylene glycol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 98.3 % Exposure time: 28 d

Method: OECD Test Guideline 301F

12.3 Bioaccumulative potential

Components:

Ethanol:

Partition coefficient: n-

: log Pow: -0.35

octanol/water

octanol/water

Phenytoin sodium:

Partition coefficient: n- :

: log Pow: 2.84

Remarks: Calculation

Benzyl alcohol:

Partition coefficient: n-

log Pow: 1.05

octanol/water

Propylene glycol:

Partition coefficient: n- : log Pow: -1.07

octanol/water Method: Regulation (EC) No. 440/2008, Annex, A.8

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.0 28.09.2024 9372657-00008 Date of first issue: 27.08.2021

П

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

12.6 Other adverse effects

Product:

Endocrine disrupting poten-

tial

This substance/mixture does not contain components considered to have endocrine disrupting properties for environment

according to UK REACH Article 57(f).

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADN : UN 1993
ADR : UN 1993
RID : UN 1993
IMDG : UN 1993
IATA : UN 1993

14.2 UN proper shipping name

ADN : FLAMMABLE LIQUID, N.O.S.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9372657-00008
 Date of first issue: 27.08.2021

(Ethanol, Pentobarbital sodium)

ADR : FLAMMABLE LIQUID, N.O.S.

(Ethanol, Pentobarbital sodium)

RID : FLAMMABLE LIQUID, N.O.S.

(Ethanol, Pentobarbital sodium)

IMDG : FLAMMABLE LIQUID, N.O.S.

(Ethanol, Pentobarbital sodium)

IATA : Flammable liquid, n.o.s.

(Ethanol, Pentobarbital sodium)

14.3 Transport hazard class(es)

Class Subsidiary risks

ADN : 3
ADR : 3
RID : 3
IMDG : 3
IATA : 3

14.4 Packing group

ADN

Packing group : III
Classification Code : F1
Hazard Identification Number : 30
Labels : 3

ADR

Packing group : III
Classification Code : F1
Hazard Identification Number : 30
Labels : 3
Tunnel restriction code : (D/E)

RID

Packing group : III
Classification Code : F1
Hazard Identification Number : 30
Labels : 3

IMDG

Packing group : III
Labels : 3
EmS Code : F-E, <u>S-E</u>

IATA (Cargo)

Packing instruction (cargo

aircraft)

Packing instruction (LQ) : Y344
Packing group : III

Labels : Flammable Liquids

366

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9372657-00008
 Date of first issue: 27.08.2021

IATA (Passenger)

Packing instruction (passen: 355

ger aircraft)

Packing instruction (LQ) : Y344
Packing group : III

Labels : Flammable Liquids

14.5 Environmental hazards

ADN

Environmentally hazardous : no

ADR

Environmentally hazardous : no

rid

Environmentally hazardous : no

IMDG

Marine pollutant : no

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : 0

UK REACH List of restrictions (Annex 17)

Conditions of restriction for the following entries should be considered: Number on list 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or

not.

UK REACH Candidate list of substances of very high

concern (SVHC) for Authorisation

The Persistent Órganic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Brit-

ain)

Not applicable

Not applicable

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9372657-00008
 Date of first issue: 27.08.2021

Regulation (EC) on substances that deplete the ozone : Not applicable

layer

UK REACH List of substances subject to authorisation : Not applicable

(Annex XIV)

GB Export and import of hazardous chemicals - Prior : Not applicable

Informed Consent (PIC) Regulation

Control of Major Accident Hazards Regulations 2015 (COMAH)

Quantity 1 Quantity 2

H2 ACUTE TOXIC 50 t 200 t

P5c FLAMMABLE LIQUIDS 5,000 t 50,000 t

Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

Full text of H-Statements

H225 : Highly flammable liquid and vapour.

H301 : Toxic if swallowed. H302 : Harmful if swallowed.

H317 : May cause an allergic skin reaction.
H319 : Causes serious eye irritation.

H351 : Suspected of causing cancer if swallowed.

H361 : Suspected of damaging fertility or the unborn child.

H361d : Suspected of damaging the unborn child.

H370 : Causes damage to organs.

H372 : Causes damage to organs through prolonged or repeated

exposure.

H412 : Harmful to aquatic life with long lasting effects.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.0
 28.09.2024
 9372657-00008
 Date of first issue: 27.08.2021

Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Chronic : Long-term (chronic) aquatic hazard

Carc. : Carcinogenicity

Eye Irrit. : Eye irritation

Flam. Liq. : Flammable liquids

Repr. : Reproductive toxicity

Skin Sens. : Skin sensitisation

STOT RE : Specific target organ toxicity - repeated exposure STOT SE : Specific target organ toxicity - single exposure GB EH40 : UK. EH40 WEL - Workplace Exposure Limits

GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency: EC-Number - European Community number: ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail: SADT - Self-Accelerating Decomposition Temperature: SDS - Safety Data Sheet: SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to compile the Safety Data

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Sheet cy, http://echa.europa.eu/

Classification of the mixture:

Classification procedure:

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

Version 4.0	Revision Date: 28.09.2024	SDS Number: 9372657-00008	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021
Flam.	. Liq. 3	H226	Based on product data or assessment
Acute	Tox. 3	H301	Calculation method
Skin	Sens. 1	H317	Calculation method
Carc.	2	H351	Calculation method
Repr.	2	H361	Calculation method
STOT	Γ SE 1	H370	Calculation method
STOT	ΓRE 2	H373	Calculation method
Aqua	tic Chronic 3	H412	Calculation method

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GB / EN